ISRCTN83450779 https://doi.org/10.1186/ISRCTN83450779

A study to describe the clinical and biological characteristics of patients with suspected or known airways disease

Submission date 17/04/2023	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 24/05/2023	**Overall study status** Ongoing	
Last Edited 17/11/2023	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
The aim of this study is to describe the clinical and biological characteristics of patients with suspected or known airways disease.

Who can participate?
Patients aged over 18 years who are referred to the complex airways service at North Bristol NHS Trust

What does the study involve?
As this study is an observational study it does not involve participants undertaking any extra visits, investigations, blood tests or medications which are not part of their usual standard care to manage their airways disease. This study will also act as a 'platform' study so the researchers will also ask each participant if they would like to be approached to take part in future studies based on the data collected.

What are the possible benefits and risks of participating?
As the study is only documenting data that relates to a participant's standard care therefore the researchers do not expect any added risks or burdens. Participants will be contributing to the growing knowledge in this area and improving care for patients with airways disease.

Where is the study run from?
Southmead Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2022 to June 2029

Who is funding the study?
1. Bristol Biomedical Research Centre (UK)
2. The Southmead Hospital Charity Fund (UK)
3. AstraZeneca (UK)

Who is the main contact?
Dr Caitlin Morgan, caitlin.morgan@nbt.nhs.uk

Contact information

Type(s)
Public

Contact name
Dr Caitlin Morgan

ORCID ID
https://orcid.org/0000-0001-7133-0195

Contact details
Learning and Research Building
Southmead Hospital
Bristol
United Kingdom
BS10 5NB
+44 (0)7739708065
caitlin.morgan@nbt.nhs.uk

Type(s)
Principal investigator

Contact name
Dr James Dodd

ORCID ID
https://orcid.org/0000-0003-4805-5759

Contact details
Learning and Research Building
Southmead Hospital
Bristol
United Kingdom
BS10 5NB
+44 (0)1174147925
james.dodd@nbt.nhs.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
321349

Central Portfolio Management System (CPMS)

55429

Study information

Scientific Title
BRistol Evaluation of novel Airways diagnostics, Therapies & Healthcare outcomEs

Acronym
BREATHE

Study objectives
Airways diseases have multiple phenotypes and by understanding the treatable and non-treatable traits of each phenotype, we will be able to improve clinical and patient-reported outcomes.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/05/2023, Westminster Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8283; westminster.rec@hra.nhs.uk), ref: 23/LO/0279

Primary study design
Observational

Study design
Single-centre longitudinal observational cohort study

Study type(s)
Other

Health condition(s) or problem(s) studied
Diagnosis and management of airways disease

Interventions
BREATHE is a single-centre, prospective longitudinal cohort study of patients who are referred to the Complex Airways Clinic at North Bristol NHS Trust (NBT). It is a platform which will include different sub-studies when they are developed in the future (with amendments reviewed by the sponsor and HRA at the time). BREATHE will record routinely collected clinical data at each stage of the multidisciplinary assessment, diagnosis and management of each patient from initial assessment until they are discharged by the service, or the study ends. The study will not include any additional investigations, questionnaires or patient visits which would not have been included as part of each patient's routine clinical management. The landscape of airway disease management will change over the next 5 years. As such BREATHE will incorporate an adaptive study design. As novel diagnostics and therapeutics emerge, it is anticipated that changes will be made to standard care which would necessitate changes to the data that is collected. If substantial changes are made, they will be assessed for inclusion in the study and request further ethical approval if necessary. The BREATHE cohort is to be a source of potential subjects for future studies.

Intervention Type
Other

Primary outcome(s)
The clinical and biological characteristics of patients with suspected or known airways disease, described using standard care clinical data over a 5-year period

Key secondary outcome(s)
1. Airways disease phenotypes and impact on disease outcomes assessed using standard care data collected over a 2-year period for each patient
2. Impact of the multidimensional clinical assessment on disease outcomes assessed by reviewing MDT outcomes over the 5-year study period
3. Response to treatment offered as part of the Complex Airways Service, assess by reviewing clinical and patient-reported outcomes over the 5-year study period
4. The prevalence of asthma mimics in this population, including inducible laryngeal obstruction (ILO), assessed by reviewing ILO diagnosis and clinical and patient-reported outcomes over a 2-year funded study period

Completion date
01/06/2029

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Known or suspected airways disease

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 Years

Sex
All

Key exclusion criteria
1. Participants who lack the capacity to consent for themselves
2. Aged below 16 years

Date of first enrolment
15/11/2023

Date of final enrolment

01/06/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
North Bristol NHS Trust

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Charity

Funder Name
Southmead Hospital Charity

Funder Name
AstraZeneca

Alternative Name(s)
AstraZeneca PLC, Pearl Therapeutics, AZ

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Funder Name
NIHR Bristol Biomedical Research Centre

Alternative Name(s)
NIHR Biomedical Research Centre Bristol, National Institute for Health Research Bristol Biomedical Research Centre, NIHR Bristol BRC, Bristol BRC, Bristol Biomedical Research Centre

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.1	16/08/2023	19/10/2023	No	No